In re Application of: Gad KEREN et al
Serial No.: 09/839,643
Filed: April 20, 2001
Office Action Mailing Date: December 16, 2008

Examiner: Nguyen, Camtu Tran
Group Art Unit: 3772
Attorney Docket: 34948

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 49-51, 59-84 and 86-112 are in this case. Claim 62 has been withdrawn from prosecution. Claims 49-51, 59-61, 63-84 and 86-112 are rejected. Claims 87, 88, 93-95 and 97 are objected to.

Claims 49-50, 59-60, 68-73, 78, 84, 86-90, 92 and 97-108 have now been amended. Claims 61, 63-67, 74-77, 79-83, 85, 91, 93-96 and 109-112 have now been cancelled.

Support for Claim Amendments

Claims 49, 59 and 103 have now been amended to describe a device having a shunt which may or may not include a valve element. Support for a valve-less shunt can be found throughout the application, see for example, paragraph [0022] which states: "All shunts, whether they include a valve or not ..." and paragraphs [0018]-[0019] of the published application.

Claim Objections

Claims 87, 88, 93-95 and 97 are objected to because they recite "a valve" which the Examiner interprets as being the valve of claim 84 or a different valve.

Claims 84, 87, 88, 93-95 and 97 have now been amended to clearly define the valve referenced in the dependent claims as the valve of claim 84.

Claim Rejections - 35 USC § 112

The Examiner has rejected claims 49-50 under 35 U.S.C. 112, second paragraph as being incomplete in omitting essential cooperative relationships of elements.

Specifically, the Examiner points out that there is an omitted structural cooperative relationship between the valve element (claim 49) and the fixation element (claim 50). Claims 49 and 50 have now been amended. The term valve has

been deleted from claim 49 and the shunt described therein has now been structurally connected to the fixation elements of claim 50, i.e. it is now clear that the fixation elements of claim 50 anchor the shunt in the septum following implantation.

The Examiner also rejects claim 75 for lacking antecedent basis for the limitation "the conditions". Claim 75 has now been cancelled thereby rendering moot any rejections with respect to this claim.

The Examiner also rejects claims 49-50 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the Examiner states that the steps recited in these claims would not decrease blood pressure in the heart. Claim 49 has now been amended to recite "A method of decreasing blood pressure in a heart chamber". As is clearly described in the instant application, implantation of a shunt between heart chambers can clearly lead to a reduction of pressure in one of the heart chambers.

The Examiner also rejects claim 89 for lacking antecedent basis for the limitation "the right ventricle". Claim 89 has now been amended to recite "a right ventricle of said heart".

Claim Rejections - 35 USC § 102

The Examiner has rejected claims 49-51, 59-61, 63-71, 73-74, 76-79, 84, 86-87, 89, 90, 92, 98-102, 111 and 112 under 35 U.S.C. 102(e) as being anticipated by Bailey et al. (US Patent No. 6,458,153).

The Examiners rejections are respectfully traversed. Claims 61, 63-67, 74-77, 79-83, 91, 93-96 and 109-112 have now been cancelled thereby rendering moot any rejections with respect to these claims. Claims 49-50, 59-60, 68-73, 78, 84-90, 92 and 97-108 have now been amended.

The Examiner states that with regards to claims 49, 59, 84, 111 and 112, Bailey et al. disclose that the CC stent valve of Figures 7-11 may be delivered into a position to repair septal defects which are atrium-to-atrium or ventricle-to-ventricle and as such, the Bailey et al. reference discloses Applicants' claimed invention.

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The present invention as claimed describes a device which is configured for positioning and anchoring within a septum between heart chambers and includes a shunt for enabling blood flow between the chambers. Such a device can be used, for example, in patients presenting with diastolic heart failure (DHF). In such patients, the present invention can be used to facilitate blood flow from the left atrium to the right atrium thereby reducing diastolic pressures in the left atrium below the excessive levels that would otherwise cause pulmonary edema.

Bailey et al. describe three device configurations, two for treating malfunctioning valves [and thus configured for positioning in a valve between two chambers (CC) or a valve between a chamber and a vessel] and one for treating septal defects (CC).

The configuration of the device of Bailey et al. designed for treating malfunctioning valves indeed include a valve which would allow blood flow therethrough since such configurations are designed to function as prosthetic valves. However, in the CC configuration designed for treating septal defects, the device of Bailey et al. does not have a valve but rather an occluding membrane since it is used for correcting septal defects and not for facilitating pressure-driven flow of blood from between two atria or two ventricles. In fact, Bailey et al. do not describe or suggest a configuration which allows flow through a septum and can be used to regulate pressure between left and right heart chambers. Furthermore, Bailey et al. do not mention a need for such a configuration or describe disorders that would require use of such a configuration.

With respect to the septal C-C configuration, Bailey teaches the following (column 5 , lines 21-32):

"The invention has multiple configurations to treat malfunctioning anatomical valves including heart and venous valves. Prosthetic cardiac valve configurations include the chamber-to-vessel for orthotopic placement at the valvular junction between a heart chamber and a vessel, and the chamber-to-chamber for orthotopic placement at the valvular junction between two heart chambers or for ***septal defect repair*** *where* ***a***

septal occluding member *is substituted for the flow regulator valve flaps.*"(emphasis added)

(column 11, lines 28-32):

"In accordance with another preferred embodiment of the invention, the CC configuration may be adapted for use in repairing septal defects. By simply substituting a membrane for the valve leaflets 26, the lumen of the stent body member 12 is occluded. The CC stent valve 40 may be delivered endoluminally and placed into a position to subtend a septal defect and deployed to occlude the septal defect." (emphasis added)

Clearly, Bailey et al. do not describe or suggest a configuration which can be used to enable blood flow between heart chambers through a septum. In fact, it can be argued that Bailey et al. teach away from a device which would enable blood flow through a septum.

In view of these remarks Applicant strongly believes that Bailey et al do not anticipate or render obvious the invention as claimed.

The Examiner has also rejected claims 49 and 50 under 35 U.S.C. 102(b) as being anticipated by king et al. (U.S. Patent No. 3,874,388).

The Examiner states that King et al. disclose a shunt implanted between a left and a right atrium and as such King et al. would perform the steps recited in these claims.

A shunt is defined as "a hole or passage which moves, or allows movement of fluid from one part of the body to another". The presently claimed method involves implantation of a shunt into a heart septum in order to facilitate movement of blood from one chamber to another.

King et al. do not describe implantation of a shunt or any element that has a shunt-like function simply because the purpose of the King et al device is to correct septal defects. In that respect, King et al utilize a pair of opposed umbrella-like

occluder elements which interlock through the septal defect to thereby seal off the defect and restore normal heart function.

The "shunt" mentioned in U.S. Patent No. 3,874,388 describes shunts in body tissue, which are caused by abnormal organ development (e.g. heart septal defects) or other disorders. In fact, King et al. repeatedly refer to correction or treatment of shunts or defects. For example, in the abstract, King et al. states that a purpose of the invention is: "eliminating the need for open heart surgery to correct a septal defect or shunt".

Thus, king et al. do not describe or suggest the present invention as claimed in claims 49 and 50.

Claim Rejections - 35 USC § 103

The Examiner has rejected claims 72, 75, 80-83, 88, 91, 93-97, 103 and 110 under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of Wolf et al. (U.S. Patent No. 6,641,610).

As is argued hereinabove, Bailey et al. does not describe or suggest the presently claimed device and method. Wolf et al. merely describe a controllable valve which the Examiner suggests can be used in combination with the device of Bailey et al.

Since the teachings of Wolf et al. are not relevant to the use and function of the septal configuration of Bailey et al. (which includes an occluder element and not a valve), Applicant is of the opinion that the present invention as claimed is patentable over the combined teachings of Bailey et al. and Wolf et al.

In view of the above amendments and remarks it is respectfully submitted that claims 49-51, 59-60, 68-73, 78 and 84-90, 92, and 97-108 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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